DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: CFN: 1125666
FEI: 3002924558

Food and Drug Administration
Baltimore District Office
Central Region
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Baltimore, MD 21201-2199
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01-BLT-027

April 25, 2001

**WARNING LETTER**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mrs. Janice Pitts, President
Janice's Kitchen
3319 Williamsburg Road
Richmond, Virginia 23231

Dear Mrs. Pitts:

During a Food and Drug Administration (FDA) inspection of your deviled crab processing facility located at 3319 Williamsburg Road, Richmond, Virginia, on April 17-18, 2001, our investigator observed serious deviations from Title 21, Code of Federal Regulations, Part 123 (21 CFR 123) Fish and Fishery Products (Seafood HACCP) regulations. These deviations, some of which were previously brought to your firm's attention, cause your cooked ready-to-eat deviled crabs to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6 (b). Your firm does not have a HACCP plan for cooked ready-to-eat deviled crab to control the food safety hazards of pathogen growth and toxin formation as a result of time/temperature abuse.

2. You must monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). Your firm did not monitor sanitation conditions and practices during the April 17-18, 2001 inspection and there were no sanitation records documenting sanitation conditions and practices for the 5-½ months preceding the current FDA inspection. This item was previously brought to your attention in a letter dated October 25, 2000.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. We may take further regulatory action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating under these conditions.

This letter does not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR 123), and the Good Manufacturing Practice regulation for food firms (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please respond in writing within 15 working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

During the inspection, a copy of your deviled crab product label was collected. According to our investigator, your deviled crab contains ingredients such as mustard, hot sauce, and sugar. However, these ingredients are not declared on your label. We also have been informed that salt and pepper, currently declared as ingredients on your product label, are no longer ingredients in the deviled crab. 21 CFR Part 101.4 (a)(1) states, in part, that ingredients required to be declared on the label of a food shall be listed by common or usual name in descending order of predominance by weight. The regulation also states, in part, that an ingredient which itself contains two or more ingredients and which has an established common or usual name, such as mayonnaise, shall be designated in the statement of ingredients on the label of such food be either declaring the established common or usual name of the ingredients followed by a parenthetical listing of all ingredients contained therein in descending order of predominance or by incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself [21 CFR Part 101.4 (b)(2)]. Please review your product label to ensure that it complies with the food labeling regulations.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, at 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at 804-379-1627, extension 14.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Virginia Department of Agriculture
and Consumer Services
Division of Consumer Protection
Office of Dairy and Food
1100 Bank Street, Suite 510
Richmond, Virginia 23219